

the following accurately and consistently:

(1) The information required for a prescription under §1306.05(a) of this chapter.

(2) The indication of signing as required by §1311.120(b)(17) or the digital signature created by the practitioner's private key.

(3) The number of refills as required by §1306.22 of this chapter.

(e) If the third-party auditor or certification organization has found that an electronic prescription application does not accurately and consistently record, store, and transmit other information required for prescriptions under this chapter, the practitioner must not create, sign, and transmit electronic prescriptions for controlled substances that are subject to the additional information requirements.

(f) The practitioner must not use the electronic prescription application to sign and transmit electronic controlled substance prescriptions if any of the functions of the application required by this subpart have been disabled or appear to be functioning improperly.

(g) If an electronic prescription application provider notifies an individual practitioner that a third-party audit or certification report indicates that the application or the application provider no longer meets the requirements of this part or notifies him that the application provider has identified an issue that makes the application non-compliant, the practitioner must do the following:

(1) Immediately cease to issue electronic controlled substance prescriptions using the application.

(2) Ensure, for an installed electronic prescription application at an individual practitioner's practice, that the individuals designated under §1311.125 terminate access for signing controlled substance prescriptions.

(h) If an electronic prescription application provider notifies an institutional practitioner that a third-party audit or certification report indicates that the application or the application provider no longer meets the requirements of this part or notifies it that the application provider has identified an issue that makes the application non-compliant, the institutional prac-

titioner must ensure that the individuals designated under §1311.130 terminate access for signing controlled substance prescriptions.

(i) An individual practitioner or institutional practitioner that receives a notification that the electronic prescription application is not in compliance with the requirements of this part must not use the application to issue electronic controlled substance prescriptions until it is notified that the application is again compliant and all relevant updates to the application have been installed.

(j) The practitioner must notify both the individuals designated under §1311.125 or §1311.130 and the Administration within one business day of discovery that one or more prescriptions that were issued under a DEA registration held by that practitioner were prescriptions the practitioner had not signed or were not consistent with the prescriptions he signed.

(k) The practitioner has the same responsibilities when issuing prescriptions for controlled substances via electronic means as when issuing a paper or oral prescription. Nothing in this subpart relieves a practitioner of his responsibility to dispense controlled substances only for a legitimate medical purpose while acting in the usual course of his professional practice. If an agent enters information at the practitioner's direction prior to the practitioner reviewing and approving the information and signing and authorizing the transmission of that information, the practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.

**§ 1311.105 Requirements for obtaining an authentication credential—Individual practitioners.**

(a) An individual practitioner must obtain a two-factor authentication credential from one of the following:

(1) A credential service provider that has been approved by the General Services Administration Office of Technology Strategy/Division of Identity Management to conduct identity proofing that meets the requirements of Assurance Level 3 or above as specified in

NIST SP 800–63–1 as incorporated by reference in §1311.08.

(2) For digital certificates, a certification authority that is cross-certified with the Federal Bridge certification authority and that operates at a Federal Bridge Certification Authority basic assurance level or above.

(b) The practitioner must submit identity proofing information to the credential service provider or certification authority as specified by the credential service provider or certification authority.

(c) The credential service provider or certification authority must issue the authentication credential using two channels (e.g., e-mail, mail, or telephone call). If one of the factors used in the authentication protocol is a biometric, or if the practitioner has a hard token that is being enabled to sign controlled substances prescriptions, the credential service provider or certification authority must issue two pieces of information used to generate or activate the authentication credential using two channels.

**§1311.110 Requirements for obtaining an authentication credential—Individual practitioners eligible to use an electronic prescription application of an institutional practitioner.**

(a) For any registrant or person exempted from the requirement of registration under §1301.22(c) of this chapter who is eligible to use the institutional practitioner’s electronic prescription application to sign prescriptions for controlled substances, the entity within a DEA-registered institutional practitioner that grants that individual practitioner privileges at the institutional practitioner (e.g., a hospital credentialing office) may conduct identity proofing and authorize the issuance of the authentication credential. That entity must do the following:

(1) Ensure that photographic identification issued by the Federal Government or a State government matches the person presenting the identification.

(2) Ensure that the individual practitioner’s State authorization to practice and, where applicable, State authorization to prescribe controlled substances, is current and in good standing.

(3) Either ensure that the individual practitioner’s DEA registration is current and in good standing or ensure that the institutional practitioner has granted the individual practitioner exempt from the requirement of registration under §1301.22 of this chapter privileges to prescribe controlled substances using the institutional practitioner’s DEA registration number.

(4) If the individual practitioner is an employee of a health care facility that is operated by the Department of Veterans Affairs, confirm that the individual practitioner has been duly appointed to practice at that facility by the Secretary of the Department of Veterans Affairs pursuant to 38 U.S.C. 7401–7408.

(5) If the individual practitioner is working at a health care facility operated by the Department of Veterans Affairs on a contractual basis pursuant to 38 U.S.C. 8153 and, in the performance of his duties, prescribes controlled substances, confirm that the individual practitioner meets the criteria for eligibility for appointment under 38 U.S.C. 7401–7408 and is prescribing controlled substances under the registration of such facility.

(b) An institutional practitioner that elects to conduct identity proofing must provide authorization to issue the authentication credentials to a separate entity within the institutional practitioner or to an outside credential Service provider or certification authority that meets the requirements of §1311.105(a).

(c) When an institutional practitioner is conducting identity proofing and submitting information to a credential service provider or certification authority to authorize the issuance of authentication credentials, the institutional practitioner must meet any requirements that the credential service provider or certification authority imposes on entities that serve as trusted agents.

(d) An institutional practitioner that elects to conduct identity proofing and authorize the issuance of the authentication credential as provided in paragraphs (a) through (c) of this section must do so in a manner consistent with the institutional practitioner’s general